# 510(k) Summary

## GMP|Surgical Solutions Inc. Laparocision™ Scope Controller System

Classification Name: Endoscope and Accessories
21 CFR 876.1500
Device Class: II
Product Code: GCJ

GMP Companies, Inc.
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Contact: Ralph Jugo, Prepared: October 25, 2004

### A. LEGALLY MARKETED PREDICATE DEVICE

The GMP|Surgical Solutions Inc. Laparocision™ Scope Controller System is substantially equivalent to the Computer Motion Inc. AESOP System and Accessories that was cleared by FDA under K931783 on November 22, 1993.

### B. DEVICE DESCRIPTION

The GMP|Surgical Solutions Laparocision™ Scope Controller System allows for surgeons to control the movement and position of conventional laparoscopes or endoscopes during thoracic, gynecologic, orthopedic, and abdominal laparoscopic procedures by means of an electromechanical arm which is controlled by either a hand controller or a foot controller. The purpose of an endoscope is to allow visualization of a surgical cavity during minimally invasive laparoscopic procedures.

The device is comprised of the following five main components:

1) The Laparocision™ Reusable Arm Assembly is the device's main component. It is attached via a clamp to an operating table and it serves to hold and control the position and movement of a laparoscope.

2) The Disposable Zoom Assembly (DZA) is attached to the distal end of the Reusable Arm Assembly, and its purpose is to hold 5mm and 10 mm diameter laparoscopes between its pinch rollers. The pinch rollers turn and act to move a laparoscope in three axes (i.e. in and out, towards the head or foot of the patient, and medially/laterally). The pinch rollers in the DZA are under the direct control of an operator via the Foot Control and the Hand Control.

3) The Foot Control and the Hand Control plug into the Reusable Arm, and by pressing control buttons on the Foot and Hand Controls, the operator can move the laparoscope in three axes.

4) The Steri-Sleeves are sterile polyethylene material bags which act to provide for protection and a sterile barrier between the reusable components (i.e. the Reusable Arm Assembly, and the Foot and Hand Controls) and the sterile field.

5) The Power Supply converts 110 alternating current voltage (VAC) to 9 volts of direct current (9VDC) required to operate the Reusable Arm Assembly.

## C. INDICATIONS FOR USE

The Laparocision™ Scope Controller System is indicated for thoracic, gynecologic, orthopedic, and abdominal procedures for the purpose of holding and controlling the movement of standard laparoscopes or rigid endoscopes within inflated surgical cavities during minimally invasive laparoscopic surgery.

## D. INTENDED USE

The Laparocision™ Scope Controller System is an electromechanical arm whose intended use is to allow a surgeon to hold and control a laparoscope's movement and position during laparoscopic surgical procedures by means of either a foot controller or a hand controller.

The trade name or proprietary name of the device which is the subject of the 510(k) premarket notification is the "GMP|Surgical Solutions Inc. Laparocision™ Scope Controller System". The common or usual name for the device is an "Endoscope Accessory".

## E. SUBSTANTIAL EQUIVALENCE SUMMARY

The GMP|Surgical Solutions Inc. Laparocision™ Scope Controller System is an electromechanical medical device that has essentially the same indications for use as the predicate device. Both devices are indicated for laparoscopic surgical procedures. The only main differences between the two devices is that the AESOP device uses a computer and software to control the devices operations, while the GMP Laparocision device does not use a computer or software to control the device's operations. The differences do not alter the intended diagnostic effect. Both devices have essentially the same intended use. A comparison of the descriptive characteristics of the GMP Laparocision device and the AESOP predicate device is sufficiently precise to assure equivalence. In-vitro performance data are provided in the form of electrical safety testing and electromagnetic compatibility (EMC) testing that was performed on both devices. The results of the performance testing demonstrate compliance with the applicable electrical safety and the data also support a determination of substantial equivalence.

As recommended by the 3-17-95 (Draft) Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology, electrical safety and Electromagnetic Compatibility (EMC) testing as per the applicable standards should be conducted and provided in a 510(k) submission.

## F. TECHNOLOGICAL CHARACTERISTICS

Both devices use electronic components to control the position and movement of laparoscopes during minimally invasive laparoscopic surgical procedures. While the details differ regarding how the control of the movement of laparoscopes is achieved, given that the AESOP device uses a computer and software while the GMP device does not, the basic technology is very similar. The differences in technology do not raise any significant questions or issues regarding the safety and effectiveness of the devices.

## G. TESTING

In-vitro electrical safety testing was conducted and met all the requirements in accordance with the standards, "UL 60601-1-UL Standard for Safety of Medical Device Equipment, Part 1: General Requirements for Safety First Edition", CSA C22.2 NO 601.1-M90 – Medical Electrical Equipment – Part 1: General Requirements for Safety General Instructions No 1; Supplement 1; 1994 R(1997)", IEC 60601-2-18 (1996-08) – Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Endoscopic Equipment Second Edition; Amendment 1, 07-2000".

In-vitro Electromagnetic Compatibility (EMC) testing was performed and met all the requirements as per "IEC 60601-1-2 (2001-09) - Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests Second Edition". In-vitro mechanical and functional testing was also performed and demonstrated that the device's design and performance requirements were met. This functional testing also demonstrates and supports a determination of substantial equivalence to the predicate device.

## H. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2005

GMP/Companies, Inc.
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K050027
Trade/Device Name: Laparocision Scope Controller System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 21, 2005
Received: January 24, 2005

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): _____

Device Name: GMP|Surgical Solutions Inc. Laparocision™ Scope Controller System

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K050027